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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,321	11/20/2000	Bonnie Gould Rothberg	15966-601 (Cura 101)	1397

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EXAMINER

VOGEL, NANCY S

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 08/26/2003

73

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/717,321

Applicant(s)

ROTHBERG ET AL.

Examiner

Nancy T. Vogel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-51, 54, 55 and 57-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This action is in response to applicant's amendment filed 6/2/03, Paper No. 22.

Claims 48-51, 54, 55, and 57-79 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 57, 63, 69, and 75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acids comprising SEQ ID NO: 1, 2, 15 and 17, vectors comprising said nucleic acid, cells comprising said vector, and composition and kits comprising said nucleic acids, does not reasonably provide enablement for nucleic acids sequences that are 95% identical to SEQ ID NO: 1, 2, 15 and 17. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

This is a new rejection necessitated by applicant's amendment to the claims filed 6/2/03.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include,

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but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are drawn to nucleic acids wherein said sequence is 95% identical to the nucleic acid sequences of SEQ ID NO:1, 2, 15 and 17. There is no functional limitation to the claims. Applicants have taught the nucleic acids of SEQ ID Nos 1, 2, 15, 17. These nucleic acids were shown to be differentially expressed in liver cells upon administration of NSAIDS, and their expression is correlated with hepatotoxicity risk associated with NSAID administration.

The claims encompass an unreasonable number of inoperative nucleic acids, which the skilled artisan would not know how to use. While the specification teaches the use of the SEQ ID NO: 1, 2, 15, and 17 as markers whose expression can serve as an indication of risk of hepatotoxicity for any NSAID, no other function has been attributed to these nucleic acids. Therefore, knowledge of these particular nucleic acids and their function as markers for hepatotoxicity does not provide predictability of the function of structurally related variants having 95% identity to said nucleic acids.

There are no working examples of nucleic acids which are less than 100% identical to the nucleic acids in SEQ ID NOs: 1, 2, 15, and 17. The skilled artisan would not know how to use non-identical nucleic acids on the basis of teachings in the prior art or specification unless they possessed the property of being expression indicators for

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the risk of hepatotoxicity for NSAIDs, as disclosed in the instant specification. The specification does not provide guidance for using nucleic acids related to (i.e. 95% identity) but not identical to the SEQ ID NOs: 1, 2, 15 and 17. The claims are broad because they do not require the claimed polypeptide to be identical to the disclosed sequence and because the claims have no functional limitation.

For these reasons, which include the unpredictability of the nature of the invention and art in terms of the lack of knowledge about function(s) of encompassed nucleic acids structurally related to SEQ ID NOs: 1, 2, 15 and 17, the one limited working example using these nucleic acids and their one function, the lack of direction or guidance for using nucleic acids that are not identical to these nucleic acids, and the breadth of the claims for structure without function, it would require undue experimentation to use the invention commensurate in scope with the claims.

Claim Objections

Claim 54 is objected to because of the following informalities: the claim is dependent on claim 1, which is cancelled. Appropriate correction is required.

Claims 48-51, 55, 58-62, 64-68, 70-74, 76-79 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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TERRY MCKELVEY
PRIMARY EXAMINER